

**Summary of the
On-Site Assessment Committee Meeting
January 14, 1998**

The On-Site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Wednesday, January 14, 1998, at 9 a.m. Eastern Standard Time (EST) as part of the Third NELAC Interim Meeting in Arlington, VA. The meeting was led by its chair, Mr. Wayne Davis of the South Carolina Department of Health and Environmental Control. A list of action items is given in Attachment A. A list of participants is given in Attachment B.

INTRODUCTION

The meeting was called to order by the chair, Mr. Davis. He announced that NELAC's Board of Directors has assigned an ombudsman to each committee, and introduced Dr. Charles Hartwig as the On-Site Assessment Committee's ombudsman. He reviewed the agenda, which included discussions of proposed changes to Chapter 3, the Assessor Training Manual, and parameter checklists.

PROPOSED CHANGES TO THE ON-SITE ASSESSMENT STANDARD (CHAPTER 3)

The committee discussed the following proposed changes to Chapter 3:

- Section 3.2.2 - Basic Qualifications - The reference to education requirements now reads "... at least a ... Bachelor's degree."
- Section 3.4.5 - Confidential Business Information (CBI) Considerations - This section now makes takes into consideration state law and reads "... in accordance with federal and state law."
- Section 3.6.1 - Assessor's Training Manual - The Assessor's Training Manual is attached to the standard as Appendix A. It ... "will serve as a reference for on-site assessment personnel."
- Section 3.6.3 - Checklists - Standardized checklists have not yet been posted, although it is the committee's intent to make the checklists a part of the standard. There was some discussion of whether the standardized checklists should be method-specific or should take a more general quality systems approach. While assessors are presumed to be experienced personnel, a method-specific checklist might serve to refresh the memory. On the other hand a general checklist might offer more flexibility for the auditor. The committee stressed the need for consistency and continuity for reciprocity between states. The committee also pointed out that audit data might be used in court. The NELAC standard does not allow the assessor any flexibility other than auditing all the methods for which the laboratory is accredited. A tiered approach, in which method-specific checklists fall under general quality requirement checklists, was suggested.

- Section 3.6.4 - Assessment Standards - This section now allows for additions by including the language, “. . . shall include, but are not limited to . . .” in reference to the areas to be evaluated in an on-site assessment. The section refers to the Assessors Manual (Appendix A) for additional information on the assessment process.
- Section 3.7.6 - Record Retention Time - This section has increased the required retention of assessment documents to “. . . a period of at least ten years, or longer if required by specific State or Federal regulations.”

ASSESSOR TRAINING MANUAL (APPENDICES A & B)

The Assessor Training Manual was drafted by an EPA contractor. It was first made available at the third annual NELAC meeting in Dallas and is now available for downloading on the NELAC Home Page. This is the first time that the committee has publicly collected comments on the manual.

As discussion of the manual progressed, it became apparent that the committee's redline changes to parts of the manual (most notably Chapter 4) had not been included in the version in the participants' meeting binders. This caused a great deal of confusion. The committee allowed comments on the manual as it was included in the meeting binder, and said that they would compare these comments to changes already made in the manual. The chair said that a corrected version would be made available on the NELAC Home Page as soon as possible. A participant noted that, although the manual is attractively formatted, it is difficult to electronically download from the NELAC web page due to its graphic elements. It was suggested that the person(s) responsible for the NELAC web page be made aware of this fact.

In general discussion of the manual it was suggested that the manual, as a standalone training document, be detached from the standard. The use of “pull-down boxes” which quote verbatim the referenced section(s) of the standard was also questioned. It was suggested that the manual reference, rather than quote, the standard. The chair asked that these suggestions be submitted to the committee in writing. General discussion also included clarification of the use of the word “should” as a reference to a non-mandatory suggestion. The committee explained that much thought had gone into the use of words such as “should,” “shall,” “may,” and “must,” and that these words are defined in the NELAC glossary. The committee stressed the importance of the receipt of written comments on the manual.

Discussion of suggestions of specific language changes followed. The committee chair noted that the committee is amenable to reasonable suggestions of changes to language. Rather than officially record specific language changes, members of the committee took notes for further committee discussion. Each of the five chapters of the Assessor Training Manual was discussed.

- Chapter 1 - Introduction - Additional discussion of the purpose of the manual ensued. Is it intended to be a training document? The chair noted that many of the suggested language changes would depend upon whether or not the manual would be detached from the Standard (Chapter 3).

- Chapter 2 - Assessment Principals and Practices - It was suggested that a subcommittee be formed to link the On-Site Assessment Committee and the Quality Systems Committee.
- Chapter 3 - Assessor Conduct - A committee member suggested that the accrediting authority send a list of NELAC assessors to NELAC laboratories prior to any assessment so that each laboratory could identify any potential conflict of interest. It was noted that this might be an issue better suited to the Database Ad Hoc Committee.
- Chapter 4 - On-Site Assessment Process - It was generally agreed that the issue of assessor training is pivotal to a good on-site assessment program. The committee noted that the manual's sections on training and qualifications are only a skeleton at this time and that additional work is required on these sections. The committee also discussed how many assessors should comprise an assessment team and agreed that the chapter's language should more clearly address this issue. Considerable discussion ensued about the distinction between a managerial review and an internal technical audit or technical systems audit. The committee stated that this distinction should be made by Chapter 5 of the standards (Quality Systems).
- Chapter 5 - Assessment Criteria - A participant expressed the belief that the Quality Systems Standard is the most important reference for the on-site assessor, followed very closely by the standardized assessor checklists. The participant then expressed the belief that the Assessment Criteria chapter of the training manual repeats the Quality Systems Standard and suggested that the committee concentrate instead on developing the assessor checklists. In response the committee discussed the incorporation of this chapter of the training manual into the checklists. The committee also stressed the difference between a standard and a guidance document. There was considerable discussion of potential confusion presented by language differences between Chapter 5 of the training manual and Chapter 5 of the standard. Again, the need for a subcommittee to ensure consistency of language between the On-Site Assessment and Quality Systems chapters was noted. The question of an assessor's qualification and responsibility to report perceived safety violations during an on-site assessment was discussed at length. The committee will review the specific language concerning health and safety.

CONCLUSION

Mr. Davis closed the meeting by stating that the committee will review the on-site assessment documents as soon as possible to be certain that current redline changes are posted on the web. He encouraged the submission of written comments to the chair by February 15, 1998. The meeting was adjourned at 4:45 p.m. EST.

ACTION ITEMS
On-Site Assessment Committee
January 14, 1998

Item No.	Action Item	Date To Be Completed
1.	Wayne Davis and Silkie Labie will discuss the formation of a subcommittee to link the On-Site Assessment Committee and the Quality Systems Committee.	
2.	Wayne Davis will review the training manual to ensure that the most recent redline corrections have been posted on the web.	

PARTICIPANTS
On-Site Assessment Committee
January 14, 1998

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